

## PATENT COOPERATION TREATY

PCT

NOTIFICATION CONCERNING  
AMENDMENTS OF THE CLAIMS(PCT Rule 62 and  
Administrative Instructions, Section 417)

From the INTERNATIONAL BUREAU

To:

Commissioner  
US Department of Commerce  
United States Patent and Trademark  
Office, PCT  
2011 South Clark Place Room  
CP2/5C24  
Arlington, VA 22202  
ETATS-UNIS D'AMERIQUE

in its capacity as International Preliminary Examining Authority

Date of mailing (day/month/year)

10 January 2001 (10.01.01)

International application No.

PCT/US99/30974

International filing date (day/month/year)

23 December 1999 (23.12.99)

Applicant

BAXTER INTERNATIONAL INC. et al

The International Bureau hereby informs the International Preliminary Examining Authority that no amendments under Article 19 have been received by the International Bureau (Administrative Instructions, Section 417).

The International Bureau of WIPO  
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1211 Geneva 20, Switzerland

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09/936098

## PATENT COOPERATION TREATY

## PCT

REC'D 14 NOV 2001

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference VAS-5395	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/30974	International filing date (day/month/year) 23 DECEMBER 1999	Priority date (day/month/year) 08 MARCH 1999
International Patent Classification (IPC) or national classification and IPC: IPC(7): A61F 2/06; A61M 29/00 and US Cl. 623/1.11; 606/194, 195, 198.		
Applicant BAXTER INTERNATIONAL INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  07 OCTOBER 2000	Date of completion of this report  07 SEPTEMBER 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  KEVIN TRUONG
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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/30974

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☐ the international application as originally filed
- ☒ the description:  
pages 1-11 , as originally filed  
pages NONE , filed with the demand  
pages NONE , filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages NONE , as originally filed  
pages NONE , as amended (together with any statement) under Article 19  
pages 12-15 , filed with the demand  
pages NONE , filed with the letter of \_\_\_\_\_
- ☒ the drawings:  
pages 1-9 , as originally filed  
pages NONE , filed with the demand  
pages NONE , filed with the letter of \_\_\_\_\_
- ☒ the sequence listing part of the description:  
pages NONE , as originally filed  
pages NONE , filed with the demand  
pages NONE , filed with the letter of \_\_\_\_\_

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☒ The amendments have resulted in the cancellation of:**

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

**5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/30974

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. statement**

Novelty (N)

Claims NONE

YES

Claims 1-20

NO

Inventive Step (IS)

Claims NONE

YES

Claims 1-20

NO

Industrial Applicability (IA)

Claims 1-20

YES

Claims NONE

NO

**2. citations and explanations (Rule 70.7)**

Claims 1-20 lack novelty under PCT Article 33(2) as being anticipated by Barone et al. Barone et al discloses in figures 9-13, a guidewire having a main portion biased into a first configuration and an end portion contiguous with one end of the main portion defined by a curved configuration having a first section with a first curvature and a second section having a second different curvature to the first section.

## NEW CITATIONS

US 5,578,072 A (BARONE et al) 26 November 1996, entire document.

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>VAS-5395</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/US 99/ 30974</b>	International filing date (day/month/year) <b>23/12/1999</b>	(Earliest) Priority Date (day/month/year) <b>08/03/1999</b>
Applicant <b>BAXTER INTERNATIONAL INC. et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ Certain claims were found unsearchable (See Box I).

3. ☒ Unity of invention is lacking (see Box II).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☒ because this figure better characterizes the invention.

3a

☐ None of the figures.

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 99/30974

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 2,3  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  
1,4,5

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

1. Claims: 1,4,5

A directable medical guidewire

2. Claim : 6

A kit comprising a guiding catheter, a directable guidewire and emplacing means.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/ 30974

## Box III TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)

A Directable Medical Guidewire having two ends and an outer surface for insertion through a lumen comprising:  
an elongate resiliently flexible body having a main portion biased into a first configuration; and, an end portion contiguous with one end of the main portion defined by a curved configuration having a first section with a first curvature and a second section having a second different curvature to that of the first section.



## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/30974

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 381 810 A (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 16 August 1990 (1990-08-16) the whole document	1,4,5
X	EP 0 778 044 A (PACESETTER AB) 11 June 1997 (1997-06-11) abstract; figure 3	1

☐

Further documents are listed in the continuation of box C.

☒

Patent family members are listed in annex.

## ° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&amp;" document member of the same patent family

Date of the actual completion of the international search

10 May 2000

Date of mailing of the international search report

16. 08. 2000

Name and mailing address of the ISA

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NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
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Authorized officer

Smith, C

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/30974

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 381810 A	16-08-1990	US 5007434 A	16-04-1991
		CA 1329095 A	03-05-1994
		DE 68918931 D	24-11-1994
		DE 68918931 T	11-05-1995
		JP 2215476 A	28-08-1990
		JP 3020514 B	15-03-2000
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EP 778044 A	11-06-1997	JP 9173464 A	08-07-1997
		US 5807339 A	15-09-1998
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**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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WO 00/053250 A1



*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## **DIRECTIONAL GUIDEWIRE**

### **Background of the Invention**

### **Field of the Invention**

The present invention relates to a guidewire for use in medical  
5 applications and, in particular, to improvements in guidewires used in the  
placement of intraluminal grafts.

### **Description of the Related Art**

The placement of prosthetic devices, such as stents and grafts,  
intraluminally and the conduct of operative procedures intraluminally has grown  
10 dramatically in recent years. In many of these placements and procedures, it is  
necessary to initially position a guidewire into a desired part of the lumen of a  
desired vessel or duct, such as a blood vessel. Once an initial guidewire is in  
place, a catheter or other tubular device may be positioned over the guidewire  
and used to convey another guidewire, prosthesis, an endoscope or a surgical  
15 instrument into the desired blood vessel or duct.

There are a variety of techniques used to position guidewires  
intraluminally, however, there are often problems encountered by medical  
practitioners in achieving the desired placement of a guidewire. One technique  
that is employed is the use of directional catheters that direct a guidewire  
20 passing therethrough in a desired direction. Such a directional catheter may, for  
example, having a curved end that directs a guidewire passing therethrough and  
exiting therefrom in a desired direction such as into a branching vessel.

### **Summary of the Invention**

According to a first aspect, the present invention consists in a directable  
25 medical guidewire for insertion through a bodily vessel or cavity, the guidewire  
comprising an elongate resiliently flexible body having a main portion which

will normally assume a straight configuration, and an end portion contiguous with one end of the main portion which will normally assume a curved configuration, the guidewire being characterized in that the curved configuration of the end portion has a first section that normally has a first curvature and a  
5 second section that normally has a second different curvature to that of the first section.

For purposes of this specification, the normal configuration of the guidewire according to the present invention is taken to be the configuration adopted by the guidewire on suspension of the guidewire, outside the body,  
10 from its end distal the end portion and allowed to hang freely. It is, therefore, expected that the normally straight main portion of the guidewire would extend substantially vertically when the guidewire was suspended from its distal end. Similarly, the normal curvature of any portion of the guidewire is the curvature adopted by the guidewire when suspended as described above. In use, the  
15 configuration assumed by portions of the guidewire will vary from their normal configuration due to the resiliently flexible nature of the guidewire as it is passed through the bodily vessel or cavity. The configuration of the guidewire during storage or distribution may also vary from that normally assumed. For example, a guidewire might be coiled and then packaged for distribution and  
20 only when removed from the packaging could it assume its normal configuration.

In one embodiment of the present invention, the second portion can be contiguous with an end of the first portion. In a further embodiment, the end portion of the guidewire can have a third section contiguous with an end of the  
25 second section that normally has a third different curvature to that of the second section. Instead of having a curvature, the third section can also be normally substantially straight relative to the curvature of the second section. It can also

be envisaged that the end portion could have a fourth or further number of curved or straight sections, depending on how tortuous vessels being treated are.

The first, second and further sections of the end portion can each normally have the curvature of a notional circle, ellipse or the like curved  
5 shapes. For example, the first section can have the curvature of a first notional circle having a first radius, and the second portion the curvature of a second notional circle having a second different radius to that of the first circle. In another example, the first portion can have the curvature of a notional circle and the second portion the curvature of a notional ellipse. In a still further example,  
10 the first portion can have the curvature of a notional ellipse and the second portion the curvature of a notional circle. In yet a further example, the first section can have the curvature of a first notional ellipse and the second section the curvature of a second notional ellipse.

The first and second section of the end portion of the guidewire can be  
15 separated by an intermediate section. The intermediate section can normally assume a straight configuration or can normally assume a curved configuration with a normal curvature different to that normally assumed by the first and second sections. If the intermediate portion normally assumes a curved configuration, the intermediate portion can have the curvature of a notional  
20 circle, ellipse or parabola.

In a further embodiment, the end portion has an angle of inflection between the first and second sections such that the first and second curved sections are of opposite curvature. The curvature of the first and second sections can also define notional planes, with the curvature of the second section  
25 being in a different notional plane to that of the first section.

In the embodiment of the invention having a normally straight intermediate portion, the normal curvature of the first section is preferably such that the intermediate portion makes an angle of between 10 and 135° to the



longitudinal axis of the normally straight portion. When the guidewire is used in the placement of intraluminal grafts in the aorta and associated iliac arteries, the angle is more preferably between 20 and 45°, and most preferably about 30°. The curvature of the second curved section is also preferably such that the

5 longitudinal axis of the intermediate portion makes an angle between 10 and 135° with a notional straight line extending from the end of the second section or an actual normally straight portion contiguous with the free end of the second section. When the guidewire is used for placement of intraluminal grafts in the aorta and associated iliac arteries, this angle is more preferably between 30 to

10 60°, most preferably about 45°.

The length of the intermediate portion can be set to suit the application of the guidewire. For use in the placement of intraluminal grafts, the length can be between 1 and 6 cm, more preferably about 3 and 4 cm.

The guidewire can be fabricated from a metal or metal alloy. For

15 example, the guidewire can be fabricated from nitinol alloy. The guidewire can be coated along its length with a suitable material to reduce friction, such as a biocompatible silicone based lubricant.

In a second aspect, the present invention comprises a kit having a guiding catheter that has disposed therein a directable medical guidewire as

20 defined herein.

In a still further aspect, the present invention comprises a method for positioning a guidewire as defined herein within a bodily vessel that is branching off a first vessel, comprising the steps of introducing a kit according to the second aspect of the present invention into the first vessel.

25 Briefly stated, there is provided that novel and enhanced guidewire iterations are provided with curvilinear end portions and methods of use of the same for endovascular grafting; for example, are taught.

According to a feature of the present invention there is provided a directable medical guidewire having two ends and an outer surface for insertion through a lumen comprising: an elongate resiliently flexible body having a main portion biased into a first configuration; and, an end portion contiguous with  
5 one end of the main portion defined by a curved configuration having a first section with a first curvature and a second section having a second different curvature to that of the first section.

According to another feature of the present invention there is provided a method of emplacing the guidewire defined by claim 1, wherein said guidewire  
10 is adapted to be suspended outside of a body having a lumen, and whereby the end distal said end portion hangs freely.

In yet another feature of the present invention there is provided a method of using the guidewire defined by claim 1, including the steps of varying the configuration of said guidewire during storage by coiling said guidewire into a  
15 spring biased state, packing said guidewire; removing said guidewire; and reconfiguring an unbiased orientation in of said guidewire in said lumen.

In yet another feature of the present application there is provided a guidewire defined by claim 1, further comprising at least one of a metal and alloy selected from the group consisting of nitinol, nickel, titanium, stainless  
20 steel, elgiloy, palladium and the like super-elastic or flexible substantially metallic or magnetic combinations.

In yet still another feature of the present invention there is provided a guidewire defined by claim 1, wherein said outer surface is coated by at least one biocompatible substance selected from the group consisting of PET, PTFE,  
25 silicone based lubricants and the like plastic-based materials.

A kit which comprises a guiding catheter having a directable medical guidewire disposed therein; a first means for emplacing the guidewire; a means

for adjusting the emplaced guidewire; and a second means for emplacing the guidewire.

#### Brief Description of the Drawings

5 Hereinafter by way of example only, preferred embodiments of the present invention are now described with reference to the accompanying drawings, in which:

FIG. 1 is a simplified diagrammatic representation of a ventral view of a patient having an aortic aneurysm bridged by a trouser graft;

10 FIGS. 2a-i show the stages of carrying out a method of intraluminally placing a trouser graft into a patient, which uses the invention, defined herein:

FIG. 3a-d are side elevational views of different embodiments of a guidewire according to the present invention;

15 FIG. 4 is a vertical sectional view of one embodiment of a possible bifurcated graft mounted over a delivery catheter for use in the method depicted in Figs. 2a-I; and

FIG. 5 is a vertical sectional view of one embodiment of a tubular graft mounted over a delivery catheter for use in the method depicted in Figs. 2a-i.

#### Detailed Description Of the Invention

20 The present invention can be used in any surgical procedure where it is necessary to direct a guidewire into a bodily vessel whether it be for the placement of an intraluminal graft of another surgical procedure. Examples of vessels in which it can be necessary to direct a guidewire include the renal, vesical and iliac arteries.

25 The present invention is hereinafter described with reference to the example of the placement of an intraluminal graft into a patient to achieve at least one of the bridging and occlusion of an aortic aneurysm. Those having a

modicum of skill likewise are cognizant of related procedures and locations, including, but not limited to thoracic situs and the like.

As seen in Figure 1, the aorta 10 branches into the right and left iliac arteries 12, 13. The aortic aneurysm 14 is located between the renal arteries 15, 16 and extend down the left iliac artery 13. One means of bridging the aneurysm 14 is to use a trouser graft 17, which is provided with a bifurcation to form a pair of short tubular extensions 19, 19a that are connected to tubular grafts 17a, 17b that extend down the iliac arteries 12, 13 respectively. One such trouser graft is described in Australian Patent Specification No AU-A-78035/94, the description of which is incorporated herein by reference.

The method for positioning an intraluminal graft will now be described with reference to Figures 2a-i. In carrying out the method an incision or puncture is made to expose the one of the femoral arteries (eg: ipsilateral), which flows from the corresponding iliac artery, and using the Seldinger needle technique, a 0.035' diameter floppy tipped flexible guidewire is inserted into and through the femoral artery and then the iliac artery 12 into the aorta 10 such that it traverses the aneurysm 14. An 8 French haemostatic sheath is then introduced over the wire to control bleeding. An angiographic catheter is then introduced to allow an angiogram to be taken of the patient to show the position of the renal arteries 15, 16 and other relevant anatomical structures in the patient.

An Amplatz extra stiff AES guidewire 23 (0.035' diameter) is then passed through the angiographic catheter into the aorta 10. After withdrawal of the angiographic catheter, the stiff guidewire 23 is left in situ. A sheath 21, preferable of 24 French, and a dilator are then introduced into the aorta 10 over the stiff guidewire 23 (see Figure 2a). A balloon catheter 24 is then introduced into the sheath 21.

As seen in Figure 4, the balloon catheter 24 is a delivery catheter which is pre-packaged with a bifurcated graft 17, having a bifurcation point 17c, and

ipsilateral extension 19, a contralateral extension 19a, and a thin catheter 25 containing a guidewire 26 extending in a first direction up through the ipsilateral tubular graft extension 19 and then in a second different direction into the contralateral extension 19a.

5           When the balloon catheter 24 is positioned within the aorta 10 correctly, the sheath 21 is partially withdrawn to free the graft so that the balloon 20 may be inflated (see Figure 2b). The inflation of the balloon 20 of catheter 24 expands the upstream end of the first graft 17 and causes it to engage its upstream end against the aorta wall above the aneurysm but downstream of the renal arteries 15,16.

10          The first graft 17 is of such a length that the short tubular extensions 19, 19a are disposed wholly within the aorta 10. The balloon 20 is then deflated but the balloon catheter is left in place for the time being (see Figure 2c). Deflation of the balloon 20 allows blood to flow down the graft 17 distending the first graft 17 and the tubular extensions 19, 19a.

15           The thin catheter 25 is preferably 3 French and resiliently flexible guidewire 26 is preferably comprised of a nitinol alloy core with a hydrophilic coating. Once the first graft 17 is in place, it is necessary to extend the guidewire 26, which is depicted in its normal configuration in Fig. 3a outside the body, has a straight main portion 50 and an end portion 51 having a curved configuration.

20          The end portion 51 is comprised of a first curved section 52 and a second curved section 53 separated by a relatively short linear intermediate portion 54. The curvature of the first curved portion 53 is preferably such that the intermediate portion 54 makes an angle of about 30° to the longitudinal axis 55 of the straight main portion 50. For other applications of the guidewire or, where required for  
25          the present illustrative application, the curvature of the first curved section can, however, be varied such that the angle lies in the range 10 to 135°. The curvature of the second curved section 53 is such that the longitudinal axis 56 of the normally straight intermediate portion is at an angle of about 45° to a notional

straight line 57 (depicted in phantom) extending from the end of the second curved section 53. As with the first curved section, the curvature of the second curved section can be varied such that the angle lies somewhere in the range of 10 to 135°. The length of the intermediate portion 54 in the depicted embodiment is 3 cm. The double curvature of the guidewire 26 allows the guidewire 26 to be guided through the contralateral iliac artery and appropriately enter the contralateral femoral artery 13a (see Fig.2c).

Once the guidewire 26 is correctly placed in the contralateral femoral artery 13a, which is cross-clamped, and an arteriotomy affected. If the guidewire 26 has been guided fully into the contralateral femoral artery 13a, the guidewire 26 is simply recovered by drawing the guidewire through the incision or puncture made in the artery 13a. If the guidewire 26 has not been guided fully along the femoral artery 13a, a snare or similar device can be introduced through the contralateral femoral artery 13a to grab the guidewire 26 and draw it back to the puncture or incision site for retrieval. Once the guidewire 26 is retrieved, the thin catheter 25 is then withdrawn via the ipsilateral side and another catheter 27 is then fed through the contralateral femoral artery 13a over the guidewire 26 until it is within the first graft 17 and reaches at least the top of the contralateral tubular extension 19a. The guidewire 26 is then withdrawn and a stiffer guidewire 30 is inserted through the contralateral femoral artery 13a into the catheter 27. The catheter 27 is then removed and a catheter sheath 21a, and a dilator are introduced over the stiff guidewire 30 (see Figure 2e).

Prior to extending the guidewire 26 into the contralateral iliac and femoral arteries, a catheter sheath (similar to catheter sheath 21) can be extended upstream through the contralateral femoral and iliac arteries to reduce any tortuosity that may be present in these arteries and so facilitate guiding of the guidewire 26 therethrough.

A second balloon catheter 24a, such as is depicted in Fig.5, on which is packaged a second tubular graft 17b is then introduced through catheter sheath 21a until its upper end is well within the contralateral tubular extension 19a at its upper end and with the iliac artery 13 at its lower end. The balloon 20a on the catheter 24a is inflated such that the upper end of graft 17b is frictionally engaged with the contralateral tubular extension 19a (see Figure 2f). The inflation of the balloon 20a on the catheter 24a supports the graft 17 during the withdrawal of the first balloon catheter 24 through the ipsilateral iliac artery 12. The balloon 20 is then deflated and the catheter 24a is maintained in place to provide continued support for the grafts 17, 17b in the aorta 10 while the third graft is positioned.

The catheter sheath 21a is then removed (see Figures 2f and 2g) and a third balloon catheter, on which is packaged a tubular graft 17a, (the third balloon catheter can be identical to that depicted in Fig.5) is introduced into the sheath 21 on guidewire 23. It is advanced until its upstream end is within the ipsilateral extension 19 and, following partial withdrawal of the sheath 21, is then deployed. The third graft 17a positioned on the third balloon catheter is thus urged at its upstream end into contact with the ipsilateral extension 19 and its downstream end into contact with the right iliac artery 12 (see Figure 2h).

The stiff guidewires 23 and 30 are now withdrawn and the contralateral incision or puncture sutured. A second angiographic examination now takes place and if the grafts 17, 17a and 17b are correctly placed and functioning, the haemostatic sheath 21 is withdrawn and the right femoral incision sutured. The result is a functioning trouser graft bridging an aneurysm as is depicted in Fig. 2i.

The operation may be carried out using a general anesthetic, an epidural anaesthetic, an epidural anesthetic, or in suitable cases, using only a local anesthetic.

Alternative guidewires to that depicted as 26 in Fig. 3a are depicted in Figs. 3b-c. Figure 3b depicts a resiliently flexible guidewire body 60 having a

normally straight main portion 50 and an end portion 51. The end portion 51 is comprised of a first curved section 61 having the curvature of a first circle, a second curved section 62 having the curvature of a different circle, and a curved intermediate portion 63 having the curvature of an ellipse. Fig. 3c depicts a  
5 resiliently flexible guidewire 70 having a normally straight main portion 50 and a curved end portion 51, with the curved end portion 51 comprised of a first curved section 71 having the curvature of a notional circle and a second curved section 72 contiguous with the end of the first curved section 71 and having the curvature of a different notional circle. Guidewires having end portions with still further  
10 curved configurations can also be envisaged.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in  
15 all respects as illustrative and not restrictive.

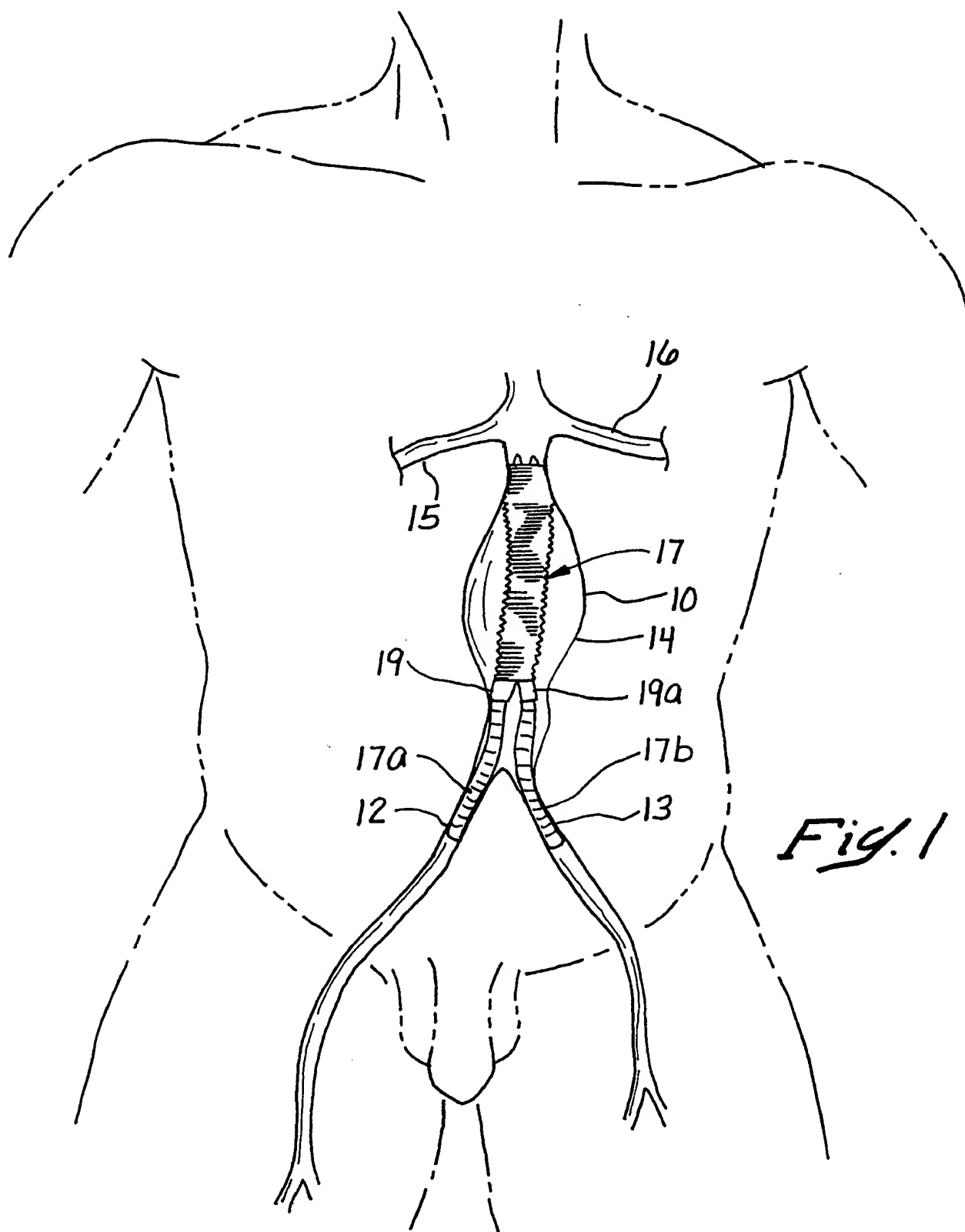


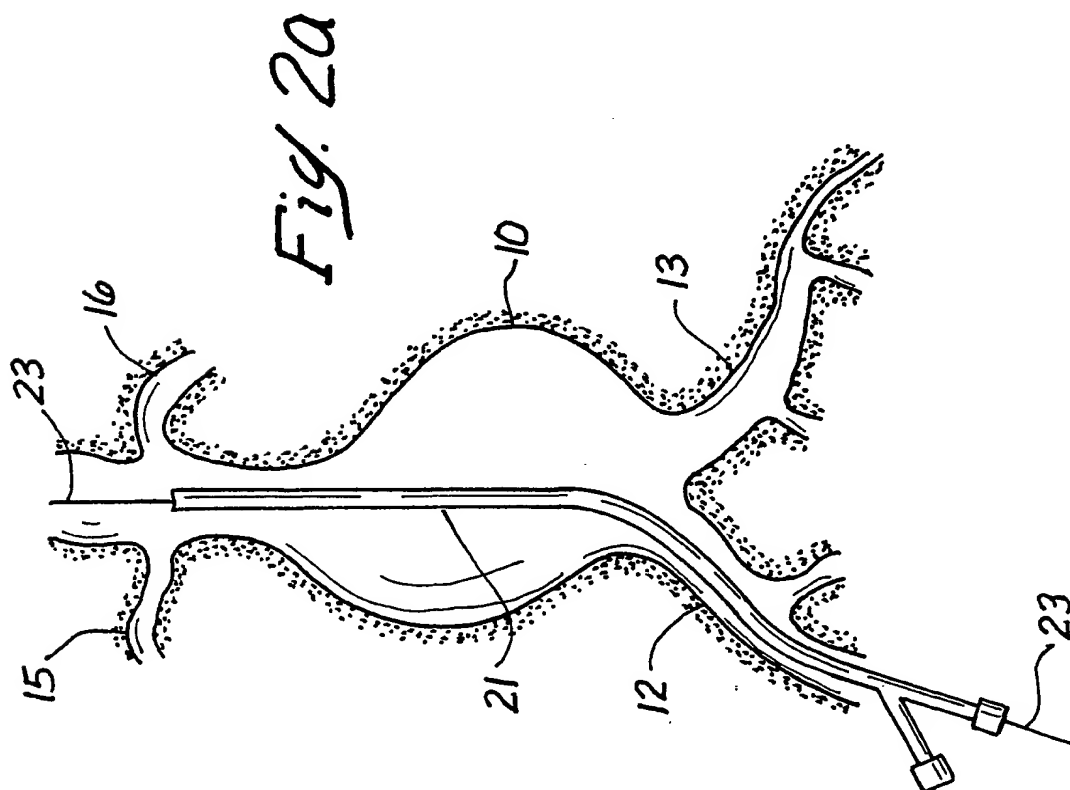
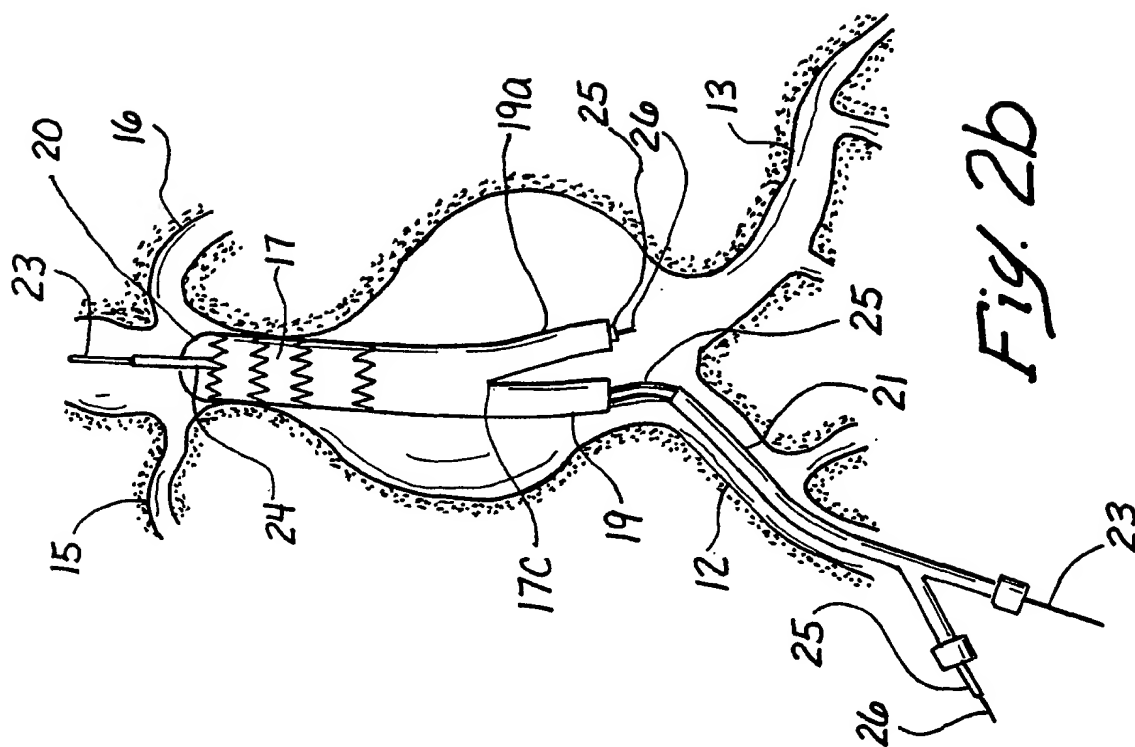
WHAT IS CLAIMED IS:

1. A Directable Medical Guidewire having two ends and an outer surface for insertion through a lumen comprising:  
5 an elongate resiliently flexible body having a main portion biased into a first configuration; and, an end portion contiguous with one end of the main portion defined by a curved configuration having a first section with a first curvature and a second section having a second different curvature to that of the first section.  
10
2. A method of emplacing the guidewire defined by claim 1, wherein said guidewire is adapted to be suspended outside of a body having a lumen, and whereby the end distal said end portion hangs freely.  
15
3. Method of using the guidewire defined by claim 1, including the steps of varying the configuration of said guidewire during storage by coiling said guidewire into a spring biased state, packing said guidewire; removing said guidewire; and reconfiguring an unbiased orientation in  
20 of said guidewire in said lumen.
4. Guidewire defined by claim 1, further comprising at least one of a metal and alloy selected from the group consisting of nitinol, nickel, titanium, stainless steel, elgiloy, palladium and the like super-elastic or  
25 flexible substantially metallic or magnetic combinations.
5. Guidewire defined by claim 1, wherein said outer surface is coated by at least one biocompatible substance selected from the group

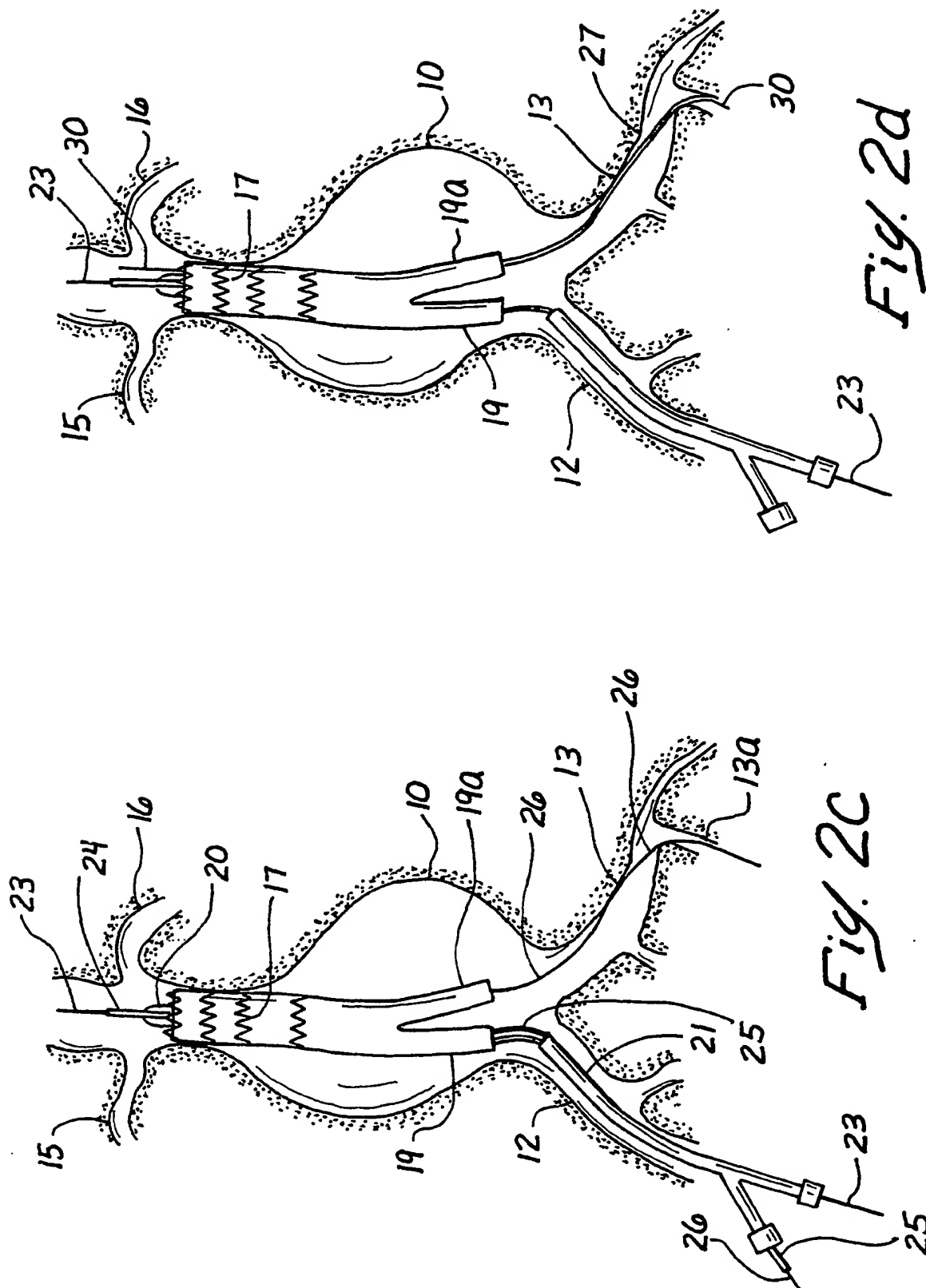
consisting of PET, PTFE, silicone based lubricants and the like plastic-based materials.

- 5           6.       A kit which comprises a guiding catheter having a directable medical guidewire disposed therein; a first means for emplacing the guidewire; a means for adjusting the emplaced guidewire; and a second means for emplacing the guidewire.

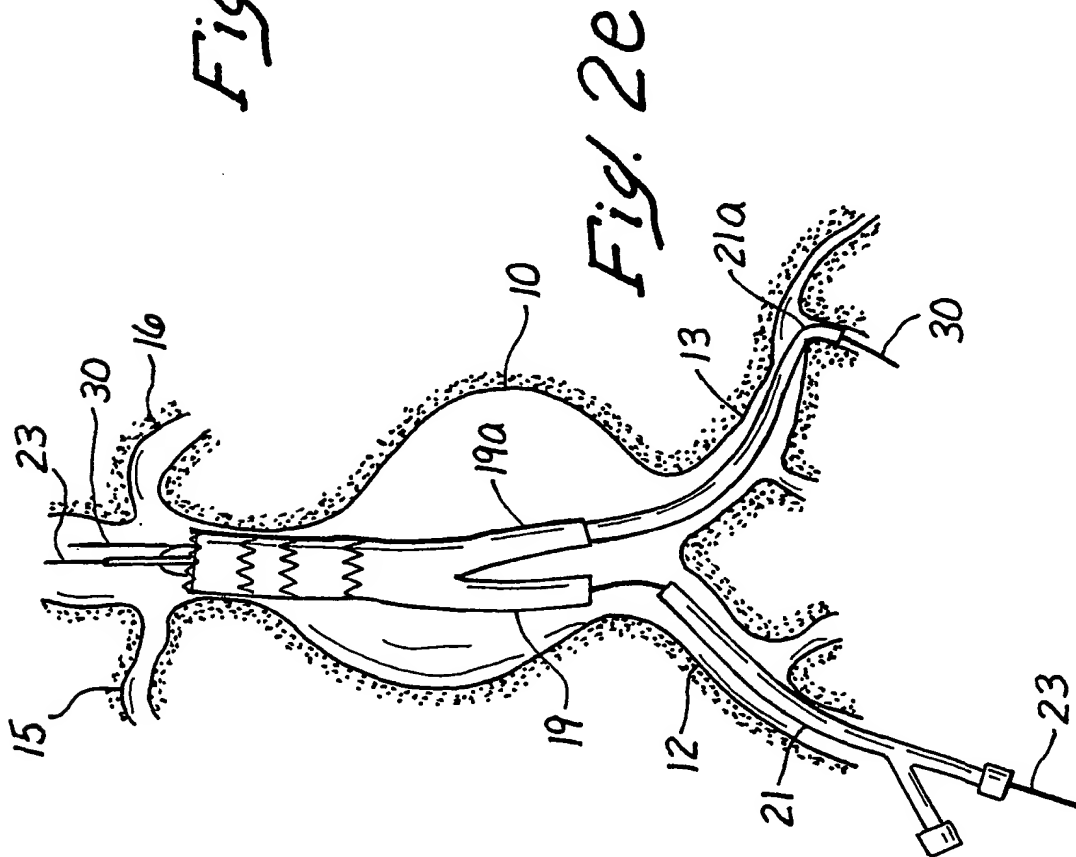
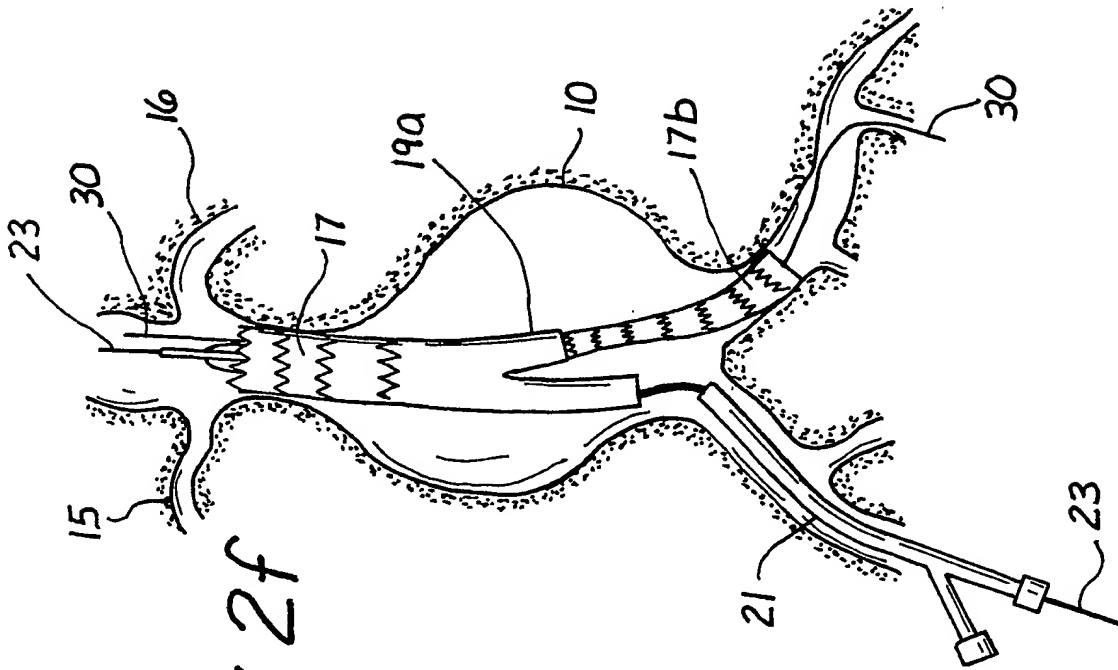


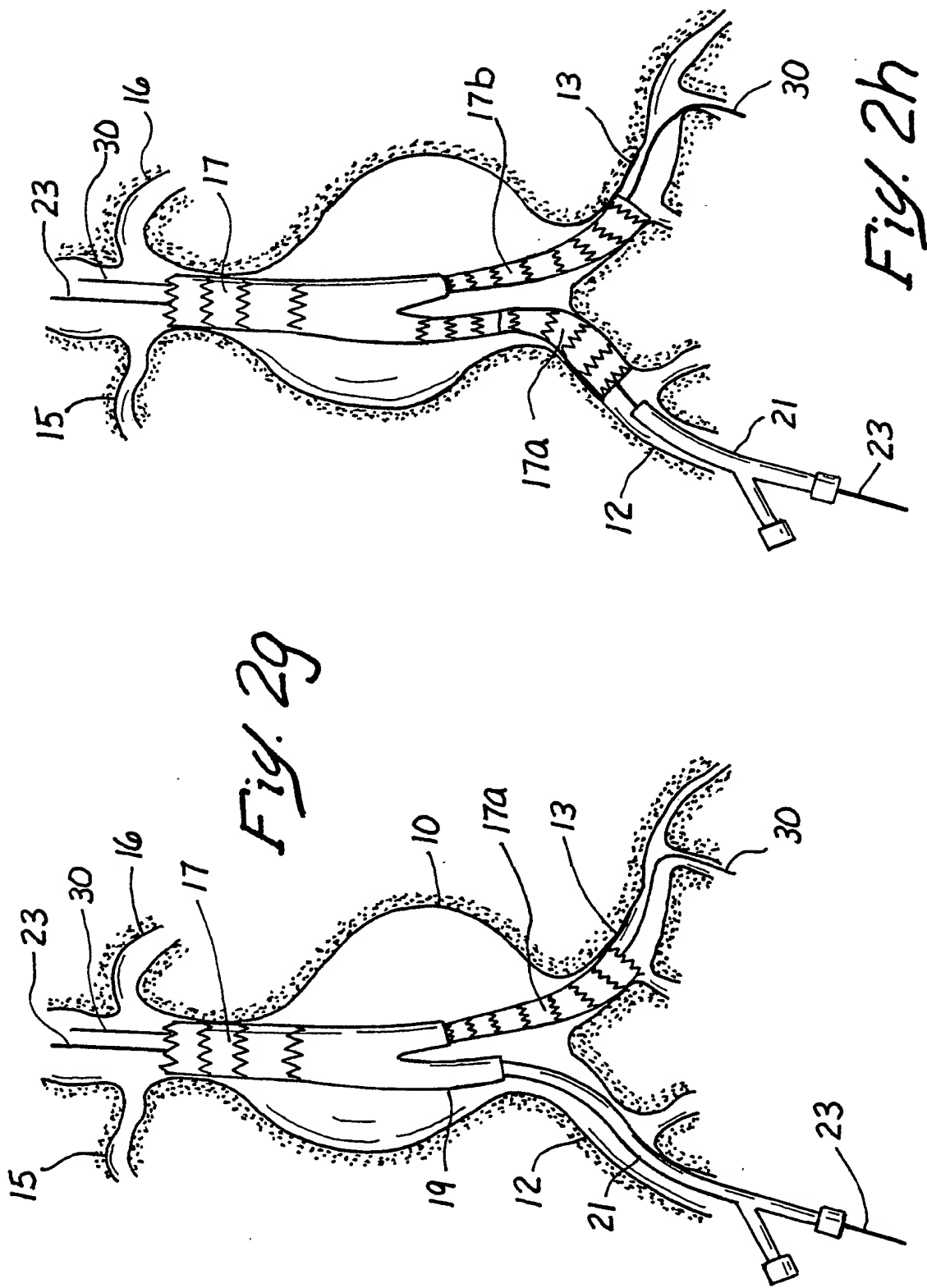


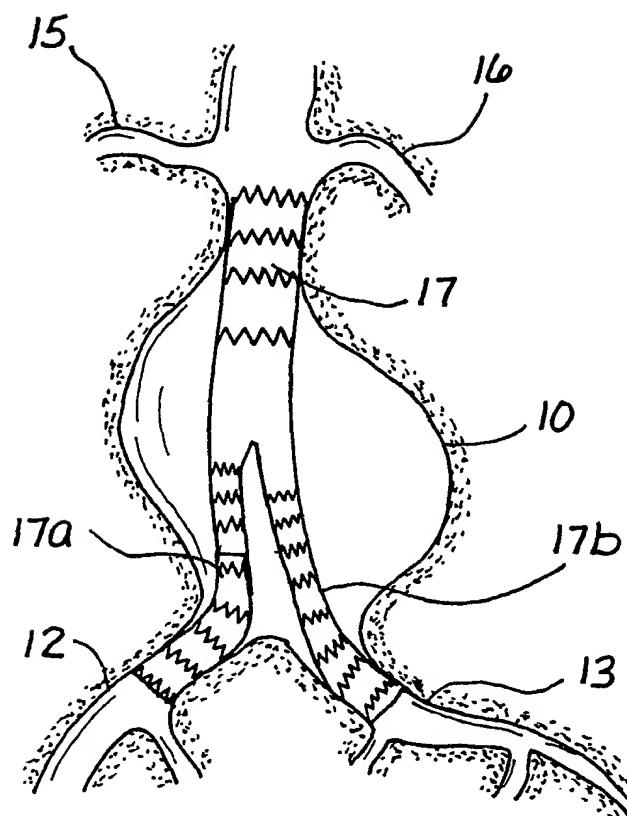
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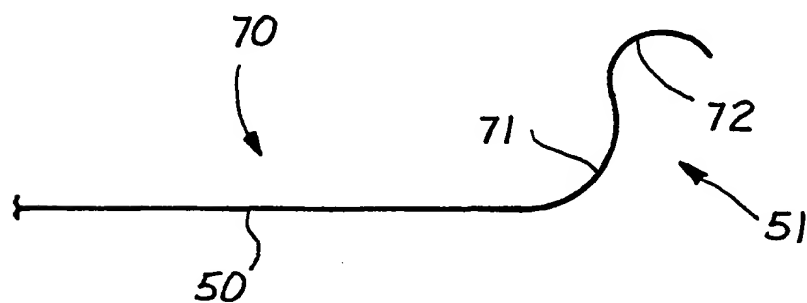
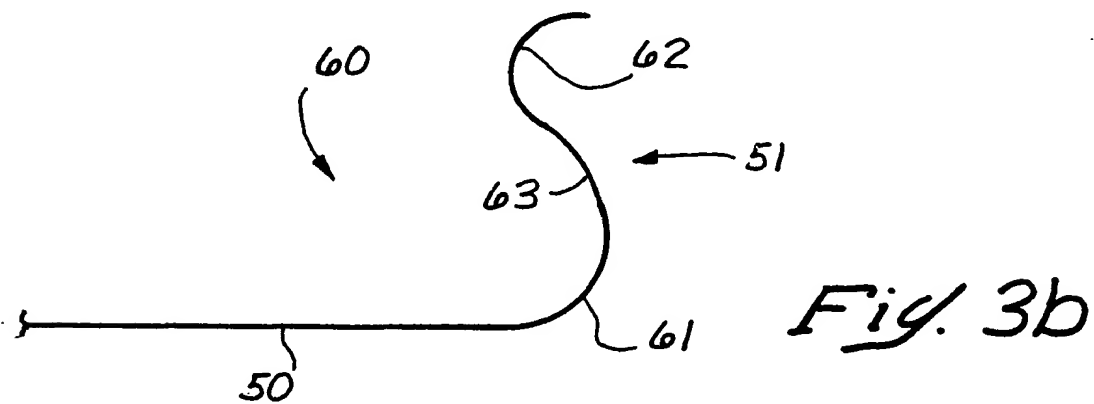
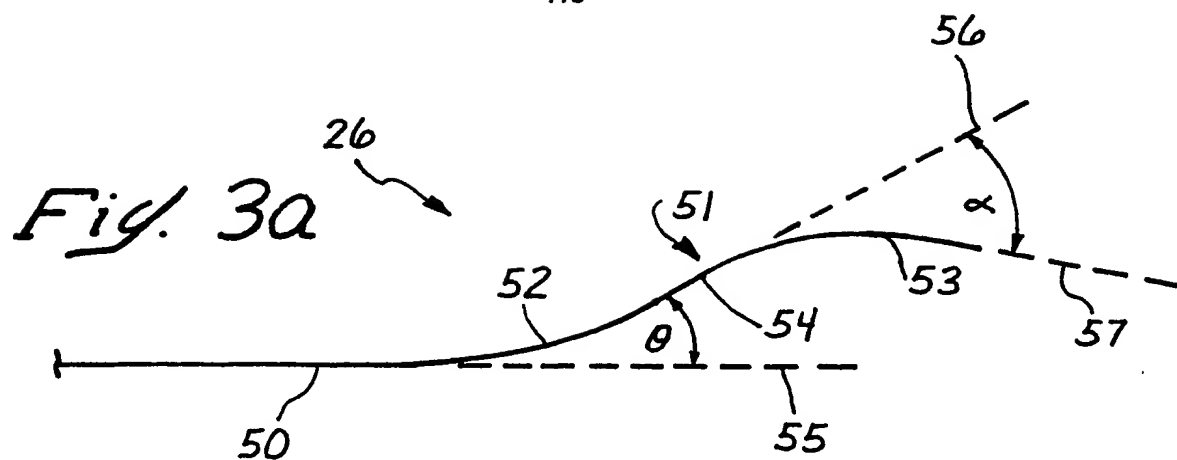


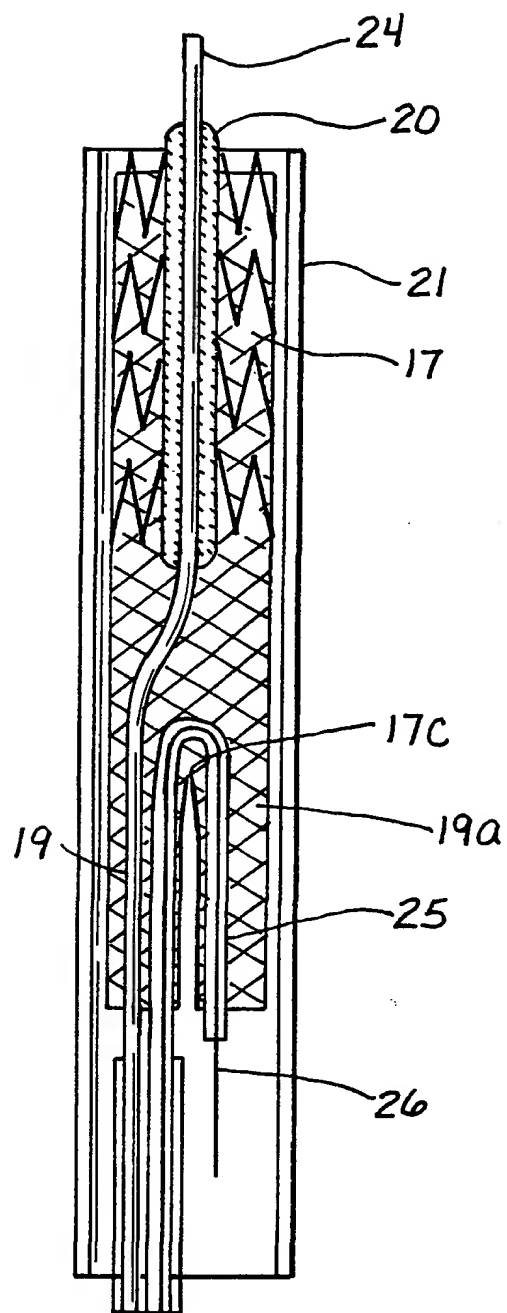


*Fig. 2i*

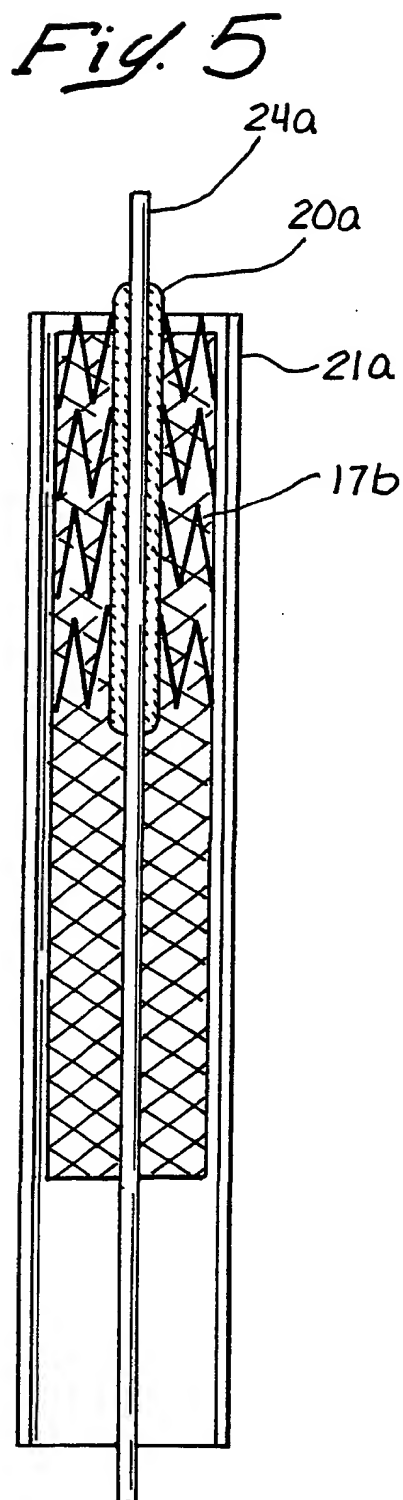


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*Fig. 4*



*Fig. 5*

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/30974

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 381 810 A (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 16 August 1990 (1990-08-16) the whole document ---	1, 4, 5
X	EP 0 778 044 A (PACESETTER AB) 11 June 1997 (1997-06-11) abstract; figure 3 -----	1

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \* & \* document member of the same patent family

Date of the actual completion of the international search

10 May 2000

Date of mailing of the international search report

16. 08. 2000

Name and mailing address of the ISA

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Authorized officer

Smith, C

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 99/30974

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 2,3  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1,4,5

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1,4,5

A directable medical guidewire

2. Claim : 6

A kit comprising a guiding catheter, a directable guidewire and emplacing means.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No  
PCT/US 99/30974

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 381810	A	16-08-1990	US 5007434 A	16-04-1991
			CA 1329095 A	03-05-1994
			DE 68918931 D	24-11-1994
			DE 68918931 T	11-05-1995
			JP 2215476 A	28-08-1990
			JP 3020514 B	15-03-2000
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EP 778044	A	11-06-1997	JP 9173464 A	08-07-1997
			US 5807339 A	15-09-1998
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